## (19) World Intellectual Property Organization International Bureau





(43) International Publication Date 15 January 2004 (15.01.2004)

PCT

## (10) International Publication Number WO 2004/004781 A1

(51) International Patent Classification7: 38/37

A61K 47/00,

(21) International Application Number: PCT/EP2003/007349

(22) International Filing Date:

8 July 2003 (08.07.2003)

(25) Filing Language:

**English** 

(26) Publication Language:

English

(30) Priority Data:

60/394,611

60/394,699 60/394,612

9 July 2002 (09.07.2002) US 9 July 2002 (09.07.2002) US 9 July 2002 (09.07.2002) US

(71) Applicants (for all designated States except US): SAN-DOZ GMBH [AT/AT]; Biochemiestrasse 10, A-6250 Kundl (AT). GRANDIS BIOTECH GMBH [DE/DE];

Grünstrasse 18, 79232 March-Hugstetten (DE).

(72) Inventors; and

(75) Inventors/Applicants (for US only): BETZ, Michael- ance Notes on Codes and Abbreviations" appearing at the begin-[DE/CH]; Jägerstrasse 1, CH-8200 Schaffhausen (CH).

STEVENS, John [GB/GB]; J.D.S. Consulting, 18 Woodland Rd, Thornton Heath CR7 7LP (GB).

- (74) Agent: GRUBB, Philip; Novartis AG, Corporate Intellectuel Property, CH-4002 Basel (CH).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LT, LU, LV, MA, MD, MK, MN, MX, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SE, SG, SK, SY, TJ, TM, TN, TR, TT, UA, US, UZ, VC, VN, YU, ZA, ZW.
- (84) Designated States (regional): Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR).

## Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidning of each regular issue of the PCT Gazette.

(54) Title: LIQUID FORMULATIONS WITH HIGH CONCENTRATION OF HUMAN GROWTH HORMONE (hgh) COMPRIS-ING 1,2-PROLPYLENE GLYCOL

(57) Abstract: The present invention relates to liquid formulations of human growth hormone (hGH, somatropin) which are storage stable, show reduced or no crystallization on storage and are suitable for administration to the human or animal body. More particularly, the invention relates to liquid formulations of human growth hormone which are stable and exhibit minimal or no crystallization when stored at least for a time at temperature above refrigeration temperatures.